

the 6 agencies (9 publications) that evaluated DPP-4 inhibitors, 2 recommended the drug not be listed or funded (CADTH, AHTAPol) and 4 recommended restricted use (PBAC, SMC, CVZ and NICE). The most common reason for agency's disinclination for listing/funding was insufficient information on the effectiveness and cost-effectiveness in the specified patient population. There are more than 100 HTAs ongoing in the endocrine nutritional and metabolic therapeutic area, approximately half of them (49 projects) concern diabetes, 21 of which evaluate pharmacological treatment of diabetes (8 countries, 11 agencies). **CONCLUSIONS:** Diabetes prevalence is on the rise, attracting increasing attention from health care agencies. Despite using similar data sources variable outcomes suggest to us that agencies are applying different weightings in their assessment process. The apparent failure to demonstrate effectiveness in specified populations suggests late segmentation by manufacturers and insufficient resourcing to generate data. This is often due to late payer requests for such analyses motivated by financial considerations. Early segmentation and engagement with payers is thus critical for HTA success.

PDB76

ETHICAL ANALYSES IN HEALTH TECHNOLOGY ASSESSMENTS OF DIABETES TREATMENTS

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OBJECTIVES: Health Technology Assessment (HTA) is mostly known for its health economic properties even though it is a multidisciplinary form of policy research examining short- and long-term consequences of the application of a health technology. There is an increased focus on ethical analyses in HTA. A descriptive analysis was conducted on diabetes HTA reports describing ethical analyses. **METHODS:** The NHS Centre for Reviews and Dissemination HTA database (<http://www.crd.york.ac.uk/crdweb/>) was searched (1991–2009) using the keyword 'diabet*'. HTA reports in English language assessing diabetes treatments were included and screened for any type of ethical analyses. **RESULTS:** Of 263 HTA reports identified in the initial search, 60 met the inclusion criteria. 4 reports included a type of ethical analysis (2 from CADTH, Canada; 1 from AHTA, Australia and 1 from NZHTA, New Zealand). CADTH conducted ethical analyses on short- and long-acting insulin analogues respectively, concluding that both types of insulin analogues did not exacerbate—might even better—the psychosocial issues of diabetes, however more quality-of-life evidence were needed. In AHTA's assessment of a continuous glucose monitoring device they described equity and access issues related to costs, and that the device could not replace standard of care, but should be used as an adjunct. NZHTA's assessment of continuous glucose monitoring devices was also related to equity concerns, concluding a need for more affordable devices. **CONCLUSIONS:** Ethical analyses are sparse in diabetes, despite stated objectives of best practice and HTA definitions. In the identified cases, ethical analyses were targeted to meet patients' needs as well as a tool to restrict access for the purpose of fair distribution in government funded health care systems. Further research on the methods of ethical analyses is warranted as well as the formulation of guidelines to fully estimate the value and ensure an optimal role for ethical analyses in HTA.

PDB77

BASAL CHARACTERISTICS OF PATIENTS BEGINNING BASAL, BASAL PLUS SHORT-ACTING, SHORT-ACTING OR PREMIX INSULIN: DATA FROM THE CREDIT STUDY

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OBJECTIVES: The ongoing Cardiovascular (CV) Risk Evaluation in people with Type-2 diabetes mellitus (T2DM) on Insulin Therapy (CREDIT) study is assessing the effect of insulin on the risk of vascular events. **METHODS:** CREDIT is a 4-year, 314 centre, non-interventional trial in North America, Europe and Asia, and includes 3031 people with T2DM who recently started basal and/or short-acting insulin, premix insulin or another insulin type. This analysis examines and compares the characteristics between groups starting basal (n = 1563), basal + short-acting (n = 444), short-acting (n = 221), premixed (n = 700) or another (n = 103) insulin. **RESULTS:** Demographic and diabetes characteristics were reasonably balanced between the insulin groups, although those receiving basal plus short-acting insulin or premix had a trend to higher baseline HbA_{1c} levels vs other insulin types (basal, 9.2 ± 1.8%; basal + short-acting, 10.1 ± 2.2%; short-acting, 9.4 ± 2.0%; premix, 9.9 ± 2.0%; other, 9.1 ± 2.0%). While the majority had previously used oral glucose lowering drugs (OGLDs) (basal, 97%; basal + short-acting, 83%; short-acting, 83%; premix, 94%; other, 85%), differences in the numbers continuing OGLDs when beginning insulin were found. Continued use of OGLDs was highest with basal insulin (89%) versus the other insulins (basal + short-acting, 36%; short-acting, 45%; premix, 62%; other, 34%). However, the distribution of types of OGLD used before insulin was similar between the groups. There are no clear patterns in CV risk profile by insulin type. Previous diagnosis of hypertension (basal, 71%; basal + short-acting, 65%; short-acting, 57%; premix, 69%; other, 72%), family history of CV disease (basal, 29%; basal + short-acting, 25%; short-acting, 21%; premix, 23%; other, 14%) and body mass index tended to be lower in the short-acting insulin group. However, triglyceride levels were lower in the short-acting and 'other' insulin groups vs premix, basal and basal plus short-acting groups. **CONCLUSIONS:** People starting different insulins have

somewhat different clinical characteristics, which may confound attempts to compare future vascular outcomes between regimens.

PDB78

DIFFERENCES IN THE CHARACTERISTICS OF PEOPLE WITH TYPE 2 DIABETES STARTING INSULIN IN THE NORTH, SOUTH AND EAST OF EUROPE: DATA FROM THE CREDIT STUDY

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OBJECTIVES: Maintaining long-term glycaemic control with insulin therapy can reduce the risk of vascular events associated with Type-2 diabetes mellitus (T2DM). The Cardiovascular (CV) Risk Evaluation in people with T2DM on Insulin Therapy (CREDIT) study is an ongoing 4-year, noninterventional trial in 314 centres across North America, Europe and Asia. **METHODS:** People with T2DM who recently started insulin were included. Here we report variation in baseline characteristics of participants in eastern vs northern vs southern Europe. **RESULTS:** Marked differences in participant characteristics were found between eastern Europe (n = 735), northern (n = 460) and southern Europe (n = 647), including proportion of males (25 vs. 61 vs. 56%), diabetes duration (8 ± 5 vs. 9 ± 6 vs. 13 ± 9 years), age (58 ± 8 vs. 63 ± 11 vs. 63 ± 11 years) and HbA_{1c} (9.7 ± 1.9 vs. 9.1 ± 2.0 vs. 9.3 ± 1.9%). Combinations of oral glucose-lowering drugs were common before insulin; sulfonylureas were dominant in eastern Europe and metformin elsewhere. Over 80% were taking non-glucose medications before insulin initiation, most commonly ARBs. People in eastern Europe had a greater family history of CV disease, were less physically active, but were not more obese (BMI: 30.7 ± 5.4 vs. 31.5 ± 6.3 vs. 29.6 ± 5.9 kg/m²). Rates of hypertension were lowest in southern Europe. HDL cholesterol in males was lowest in northern Europe and in females was highest in eastern Europe. LDL cholesterol was highest in southern Europe. Total cholesterol levels were lowest, but triglyceride levels were highest in northern Europe. Smoking was less prevalent in eastern Europe. Most people began with a basal insulin regimen (60 vs 63 vs. 62%); more people used meal-time insulin in eastern Europe (19 vs. 11 vs. 17%) and pre-mixes in northern Europe (22 vs. 28 vs. 13%). **CONCLUSIONS:** Baseline characteristics of people starting insulin reveals some striking differences between European regions; how these translate into CV events as the study progresses will be of interest.

PDB79

DO PEOPLE BEGINNING BASAL INSULIN HAVE A DISTINCT CLINICAL PROFILE COMPARED WITH THE OVERALL POPULATION IN THE CREDIT STUDY?

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OBJECTIVES: The Cardiovascular Risk Evaluation in people with Type-2 diabetes mellitus (T2DM) on Insulin Therapy (CREDIT) study is evaluating the effect of insulin on the risk of vascular events, which can be reduced via long-term glycaemic control. **METHODS:** CREDIT is a 4-year, 314 centre, non-interventional trial in North America, Europe and Asia. It includes 3031 people with T2DM who had recently started basal, short-acting or premix insulin, over half of whom received basal insulin alone (n = 1563). This analysis examines the baseline characteristics amongst the subgroup initiating basal insulin after oral failure and compares them with those of the wider CREDIT population. **RESULTS:** The mean starting dose of basal insulin was 14.7 IU/day, administered once daily in 86% of participants. Of these, 61% took their injection at bedtime, 21% at breakfast, 17% at dinner and 1% at lunch. Over 90% used pen devices, split equally between disposable (46%) and reusable devices (45%). Demographic and clinical characteristics, including macrovascular disease and cardiovascular risk profiles, were broadly similar between the basal insulin subgroup and the overall group of participants (basal insulin subgroup vs total population: males, 48 vs 51%; age, 62 ± 11 vs 61 ± 10 years; T2DM duration, 10 ± 7 vs 11 ± 8 years; HbA_{1c}, 9.2 ± 1.8 vs 9.5 ± 2.0%; prior use of oral glucose lowering drugs [OGLDs], 97 vs 93%). Use of OGLDs with insulin tended to be higher in the basal insulin subgroup than in the total population (any OGLD, 89 vs. 70%; biguanides, 64 vs. 50%, sulfonylureas, 63 vs. 43%). **CONCLUSIONS:** The one notable difference between the groups was that those beginning basal insulin alone were more heavily treated with OGLDs beforehand than in the overall population, most commonly biguanides and sulfonylureas. This suggests that they required no lesser intensity of glycaemic management than people starting on other types of insulin.

PDB80

MEASURING GLYCOSYLATED HAEMOGLOBIN LEVELS IN PATIENTS WITH DIABETES: IMPACT OF LOWER QOF TARGETS ON ACHIEVEMENT OF CLINICAL INDICATORS AND QOF POINTS

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OBJECTIVES: The 2008/09 Quality and Outcomes Framework (QOF) indicators for measuring glycosylated haemoglobin (HbA_{1c}) levels are DM20 and DM07, which measure percentage of diabetic patients with HbA_{1c} of either 7.5 or less or 10 or less respectively. New QOF clinical indicators have been agreed for 2009/10: DM23